

# ATTACHMENT 8



445 Apollo Beach Blvd, Apollo Beach, FL 33572  
Phone: (813) 645-2855  
FAX: (813) 645-2856

Date: December 17, 2015

Document Mail Center (W066-06)  
Center For Devices and Radiological Health  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Re: K143619

Dear Dr. Wen:

Please allow this letter to serve a notice of our client's (Rebotix, LLC) intent to withdraw the above mentioned 510(k) Premarket Notification. We will require additional time in order to address the requests for additional information dated June 23, 2015. Due to the nature of the testing and information requested we will not be able to respond within the 180 day allotted timeframe. It is our intent to resubmit the 510(k) at a later date once the data has been collected and compiled.

Thank you for your time and consideration.

Best regards,

A handwritten signature in black ink that appears to read "Ryan Burke".

Ryan Burke  
Regulatory Correspondent (K143619)

Exhibit  
DX 257